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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,264	03/12/2004	Don Fishbein	52427-AA/JPW/GJG	8229

7590 06/30/2006

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EXAMINER	
LEWIS, AMY A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,264	FISHBEIN, DON	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Case

Due to the newly applied rejections as summarized below, the finality of the previous office action, mailed 3/1/2006, is hereby withdrawn. The after final amendment, filed 5/19/2006, has been entered.

The Remarks, filed 19 May 2006, have been entered into the application. Claims 30-45, as filed 25 November 2005, are presented for examination.

Response to Applicants' Arguments/Remarks:

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Double Patenting:

1) Provisional rejection of claims 30-45 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-28 of copending US Patent Application Serial No. 10/799197, has been withdrawn in view of the terminal disclaimer, approved 25 May 2006.

2) Rejection of claims 30-45 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-20 of U.S. Patent No. 6,576,659 B1, has been withdrawn in view of the terminal disclaimer, approved 25 May 2006.

3) Rejection of claims 30-45 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-31 of U.S. Patent No. 6,828,313 B2, has been withdrawn in view of the terminal disclaimer, approved 25 May 2006.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4) Claims 30-34 and 36-40, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Patent No. 6,011,023), in view of Roberts (US Patent No. 4,112,123).

Clark et al. teach the administration of angiostatic steroids in the treatment of burns (see: abstract; col. 2, lines 58-66; claims 1-2). The reference cites oxandrolone as a compound to be used in such treatment (see: col. 25, line 27). The reference teaches various topical and systemic delivery formulations, including topical, oral, and injectable, and dosage ranges from 10-1000mg (see: col. 13, lines 59-61; cols. 18-20, Examples 4-8).

Roberts teaches that abnormal catabolic states can be induced by traumas, such a burns, which induce a necessity for a high caloric intake, and that such patients often suffer severe body weigh loss during the abnormal catabolic state (col. 1, lines 15-45).

Roberts teaches a nutritionally balanced food composition for oral ingestion by patients with such abnormal catabolic states, which contains a water soluble, suspendable, undenatured protein (see: abstract; col. 11 and 12, Tables 1-4; claims 1-25).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to treat burn induced weight loss with oxandrolone and additional protein supplementation because it is known to treat burn patients with oxandrolone (as taught by Clark et al.), and it is known that the same population of patients, i.e. burn patients, suffer from an abnormal catabolic state which results in severe weight loss (as taught by Roberts). The skilled artisan would have been motivated to do so, and would have had a reasonable expectation of success, because it is the same population of patients. It would also have been obvious to administer protein supplementation along with the oxandrolone, having been taught by Roberts that it is known to treat abnormal catabolic states resulting in severe weight loss, such as burns, through nutritional compositions containing protein. Therefore, the invention as a whole would have been prima facie obvious.

5) Claims 30-34 and 36-41, and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Patent No. 6,011,023), in view of Roberts (US Patent No. 4,112,123) as applied to claims 30-34 and 36-40, 42 and 43 above, and further in view of Almada et al. (US Patent No. 5,726,146).

Clark et al. and Roberts are applied as above.

Almada et al. teach dietary supplement formulations containing protein source(s) which increase lean body mass without concomitant increase of body fat mass (abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to treat burn induced weight loss with oxandrolone and additional protein supplementation because it is known to treat burn patients with oxandrolone (as taught by Clark et al.), and it is known that the same population of patients, i.e. burn patients, suffer from an abnormal catabolic state which results in severe weight loss (as taught by Roberts). The skilled artisan would have been motivated to do so, and would have had a reasonable expectation of success, because it is the same population of patients. It would also have been obvious to administer protein supplementation along with the oxandrolone, having been taught by Roberts that it is known to treat abnormal catabolic states resulting in severe weight loss, such as burns, through nutritional compositions containing protein. In addition, it would have been obvious that the weight gained is lean body mass, having been taught by Almada et al., that such protein supplements result in increased lean body mass. Therefore, the invention as a whole would have been prima facie obvious.

6) Claims 30-34 and 36-40, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Patent No. 6,011,023), in view of Roberts (US Patent No. 4,112,123), as applied to claims 30-34 and 36-40, 42 and 43 above, and further in view of Folkman et al. (US Patent No. 5,021,404).

Clark et al. and Roberts are applied as above.

Folkman et al. teach sustained release formulations of angiostatic steroids (see: anstract; col. 2, lines 38-45; col. 4, lines 50-57).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a sustained release formulation of the claimed composition. The skilled artisan would have been motivated to make a sustained release formulation of oxandrolone, by the desire to have a convenient delivery system which dispenses the therapeutic agent in a controlled, constant rate. The person of ordinary skill in the art would have had a reasonable expectation of success in making sustained release oxandrolone, having been taught by the prior art (Folkman et al.) that sustained angiostatic steroid compositions are known. Therefore, the invention as a whole would have been prima facie obvious.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7) Claims 30-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the limitation "a therapeutically effective amount of oxandrolone" however the claim does not recite the desired effect. The connection that the amount is effective for promoting weight gain after weight loss resulting from post-

burn catabolism is implied; however, an implied connection does not meet the "distinctly claiming" requirement of 35 U.S.C. 112, second paragraph. To overcome this rejection, it is suggest that after the phrase "a therapeutically effective amount of oxandrolone", insert the phrase --effective for promoting weight gain in said patient--.

Conclusion

Claims 30-45 are rejected. No claims are allowed.

Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Ardin H. Marschel 6/25/06
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